

January 11, 2000

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

5226 '00 JAN 12 P2:38

Re: Docket No. 99D-5347, "Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products from Xenotransplantation Product Recipients and Their Close Contacts"

To whom it may concern:

I am writing to express my concern that the proposed guidelines to protect the blood supply from contamination by zoonotic diseases are inadequate and problematic.

The prospect of maintaining a registry of patients who have received xenografts, and preventing those individuals from donating blood is riddled with problems. Obvious privacy issues make the prospect of such a registry forbidding at the outset. It is unlikely that it would be legally possible to require individuals to agree to be listed in such a registry. Moreover, as blood donation does not require validation, individuals could easily donate under different identities.

Unlike HIV, for example, which is now detectable in blood with very reliable tests, some zoonotic disease agents may be completely undetectable until it is too late and disease manifests unexpectedly, perhaps not until the infectious agent is widespread in the human population.

The human blood supply has unfortunately already been jeopardized, because humans have been receiving animal cells and tissues for years. The hindsight proposal of attention to the risk of zoonotic disease from xenotransplantation does not go far enough. Instead of such measures that finally acknowledge the risks of xenotransplants, but fail to adequately protect us from those risks, xenotransplants should instead be banned. We should instead implement public policy designed to encourage an increase in the number of organs harvested from human beings (most of which, sadly, are now burned or buried) combined with a preventive approach to health and wellness, recognizing that the vast majority of diseases addressed by transplantation are caused by factors that are almost entirely preventable.

Sincerely,

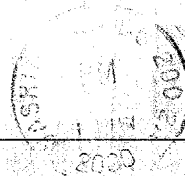
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